

## I. Remarks

Claims 1-11 are pending in the subject application.

Claims 1, 2, 6, and 10 have been amended with this response. Support for the amendment to claim 1 is found throughout the instant specification and particularly at paragraphs [0018], [0089], [0090], [0091], and Example 1. Support for the amendment to claim 2 is found throughout the instant specification and particularly at paragraphs [0011] and [0012]. Support for the amendment to claim 6 is found throughout the instant specification and particularly at paragraphs [0014] and [0015]. Support for the amendment to claim 10 is found throughout the instant specification and particularly at paragraph [0279]. Applicant asserts the above amendments clarify the instant claims by rearranging certain claim language and by explicitly providing previously implicit features. They do not change the nature of the instant methods. Therefore, these amendments do not add new matter and respectfully requests their entry.

Claim 11 has been newly added with this response. Support for this new claim is found throughout the instant specification and particularly at paragraphs [0017], [0089], [0090], [0091], and Example 2. Applicant asserts the added claim does not add new matter and respectfully requests entry of said claim.

## II. Claim rejections under 35 U.S.C. § 102

Claims 1-9 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Mazzara et al. (U.S. Patent No. 5,747,324) (May 5, 1998) hereinafter referred to as "Mazzara". Applicant respectfully traverses.

Mazzara allegedly anticipates the instant claims because the Mazzara utilizes a step of detecting a polypeptide by reacting said polypeptide with anti-HIV serum. The Office concludes that this step identifies a polypeptide correlating with a phenotype of interest and thus anticipates the instant invention. Mazzara does not and cannot anticipate claims 1-9 or newly added claim 11 because Mazzara does not teach the comparison step required by the instant claims.

The instant invention requires the comparison of two lists, wherein said comparison enables the identification of a polypeptide correlating with a phenotype of interest. This comparison was present in

*In re: Nicolette*

USSN: 09/955,656

Filed: September 18, 2001

Page 3

the claimed methods prior to their present amendment through the language "common to a list of characterized genes...and a list of characterized polypeptides..." However, in the interest of furthering prosecution, Applicants have amended the claims to emphasize the importance of this comparison step by explicitly stating said step in claim 1 and newly added claim 11.

In contrast to the instant invention, Mazzara does not teach, suggest, or utilize such a comparison. Therefore, Applicant respectfully asserts that Mazzara does not anticipate the instant invention and respectfully requests withdrawal of the rejection.

### **III. Claim rejections under 35 U.S.C. § 103**

Claim 10 stands rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Mazzara et al. (U.S. Patent No. 5,747,324) (May 5, 1998) in view of Greenspan (U.S. Patent No. 6,551,575 B1) (April 22, 2003). Applicant respectfully traverses.

As stated above, the amendments made to the instant claims render the rejection based on Mazzara moot. Since the primary reference fails to provide the instant invention of claims 1-9 or newly added claim 11, a combination of Mazzara with Greenspan fails to provide claim 10. Therefore, the obviousness rejection set forth above is moot. Applicant respectfully requests withdrawal of this rejection.

### **IV. Claim rejections under 35 U.S.C. § 112**

Claims 1-10 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses.

The amendments made to the instant claims render this rejection moot. Applicant therefore respectfully requests withdrawal of this rejection.

**V. Claim amendments under 37 C.F.R. § 1.121**

1. (Currently amended) A method to identify the polypeptide correlating with a phenotype of interest, ~~wherein the polypeptide specifically recognizes and binds a serum antibody~~, said method comprising:  
a) binding serum selected from at least one subject with a phenotype of interest to one or more relevant cells or tissues,

b) comparing lists (i) and (ii), wherein list (i) comprises a list of genes differentially expressed in said cells or tissues and list (ii) comprises a list of polypeptide characteristic data for the identifying the polypeptide correlating with a phenotype of interest, wherein the polypeptide that specifically recognizes and binds a serum antibody in said serum obtained from a subject common to a list of characterized genes,

~~wherein a polypeptide common to both lists correlates with the phenotype of interest said genes are differentially expressed in one or more relevant cells or tissues and a list of characterized polypeptides, thereby identifying said polypeptide correlating with said phenotype of interest.~~

2. (Currently amended) The method of claim 1 or 11, wherein the genes of the list (i) are characterized by properties of the gene product, wherein the said properties are selected from the group consisting of specific reactivity with the serum antibody, highly expressed in the relevant cell line or tissue, little or no detectable expression in the relevant cell line or tissue, and uniquely expressed in the relevant cell line or tissue.

3. (Original) The method of claim 2, wherein two or more properties characterize the properties of the gene product.

4. (Original) The method of claim 2, further comprising the property of molecular weight.

5. (Original) The method of claim 3, further comprising the property of molecular weight.

6. (Currently amended) The method of claim 1 or 11, wherein the list (ii) of polypeptide characteristic[[s]] data of the proteins of the list is [[a]] selected from mass, reactivity with the serum antibody, peptidase digestion pattern, enzymatic digestion pattern and MALDI-TOF selection criteria.

*In re: Nicolette*

USSN: 09/955,656

Filed: September 18, 2001

Page 5

7. (Original) The method of claim 6, wherein two or more properties characterize the properties of the gene product.

8. (Original) The method of claim 6, further comprising the property of molecular weight.

9. (Original) The method of claim 7, further comprising the property of molecular weight.

10. (Currently amended) The method of claim 6, wherein MALDI-TOF selection criteria are selected from the group consisting database selection, species, type of digest, number of miscleavages, molecular weight range, contamination indication, CNBr cleavage pattern, and mass accuracy.

11. (New) A method to identify the polypeptide correlating with a phenotype of interest, said method comprising:

a) binding serum selected from at least one subject with a phenotype of interest to one or more relevant cells or tissues

b) binding serum selected from at least one subject without said phenotype of interest to one or more relevant cells or tissues

c) comparing lists (i) and (ii), wherein list (i) comprises a list of genes differentially expressed in said cells or tissues and list (ii) comprises a list of polypeptide characteristic data for the polypeptide that binds to a serum antibody differentially present or absent between the serum in (a) and the serum in (b),

wherein a polypeptide common to both lists correlates with the phenotype of interest, thereby identifying said polypeptide correlating with said phenotype of interest.

*In re: Nicolette*  
USSN: 09/955,656  
Filed: September 18, 2001  
Page 6

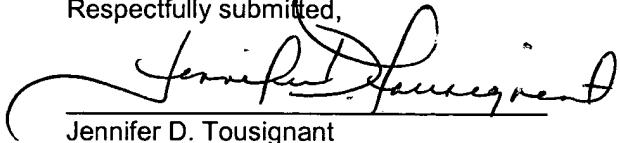
**VI. Summary**

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Date: 2/18/05

GENZYME CORPORATION  
15 Pleasant Street Connector  
P.O. Box 9322  
Framingham, MA 01701-9322

Respectfully submitted,



Jennifer D. Tousignant  
Agent for Applicant  
Registration No. 54,498  
Telephone: (508) 270-2499  
Facsimile: (508) 872-5415